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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,408	01/23/2002	Takashi Sera	109845-139	3337

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300 PARK AVENUE  
NEW YORK, NY 10022

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,408	SERA, TAKASHI	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-86 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method of preparing an artificial transcription factor (ATF).
- II. Claims 11-16, drawn to a method of preparing ATF wherein the DNA binding domain is prepared by a modular assembly method.
- III. Claims 17-19, drawn to host cells.
- IV. Claims 20-31, drawn to a method of preparing ATF comprising scanning a library of ATFs.
- V. Claims 32-33, drawn to a method of preparing ATF comprising a scanning method wherein the DNA binding domain is prepared by a modular assembly method.
- VI. Claims 34-36, drawn to host cells.
- VII. Claims 37 and 40-44, drawn to a method of preparing a protein.
- VIII. Claims 38-44, drawn to a method of preparing a protein including preparing a scanning library of said proteins.

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- IX. Claims 45-47, drawn to a method of preparing a protein with the DNA binding domain prepared by a modular assembly method.
- X. Claims 48-49, drawn to a host cell.
- XI. Claim 50 an isolated, artificial zinc finger protein (ZFP).
- XII. Claims 51-53, drawn to a nucleic acid.
- XIII. Claim 54, drawn to a method of preparing a ZFP.
- XIV. Claim 55, drawn to an isolated fusion protein.
- XV. Claim 56, drawn to an isolated fusion protein with the second segment binding to a divalent ligand.
- XVI. Claim 57, drawn to an isolated fusion protein with three domains.
- XVII. Claims 58-60, drawn to a nucleic acid, expression vector and host cell.
- XVIII. Claim 61, drawn to a method of preparing a ZP.
- XIX. Claims 62-63, drawn to a method making a nucleic acid encoding a ZFP.
- XX. Claim 64, drawn to a method of making a nucleic acid having four or more zinc fingers domains.
- XXI. Claims 65-66, drawn to an expression vector and host cell.
- XXII. Claim 67, drawn to a method of preparing a ZFP.

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- XXIII. Claim 68, drawn to a method of designing a ZFP.
- XXIV. Claim 69, drawn to a method of designing a multi-domain ZFP.
- XXV. Claim 70, drawn to a method of binding a target nucleic acid with an artificial ZFP.
- XXVI. Claim 71, drawn to a method of binding a target nucleic with a multi-domained ZFP.
- XXVII. Claim 72, drawn to a method of modulating expression of a gene comprising a regulatory control element of said gene.
- XXVIII. Claim 73, drawn to a method of modulating expressing of a gene comprising a fusion protein of a ZFP.
- XXIX. Claim 74, drawn to a method of altering genomic structure.
- XXX. Claim 75, drawn to a method of inhibiting viral replication.
- XXXI. Claim 76, drawn to a method of inhibiting viral replication comprising encoding a fusion protein.
- XXXII. Claim 77, drawn to a method of contacting a eukaryotic cell with a divalent ligand.
- XXXIII. Claims 78-79, drawn to an artificial transposase.

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XXXIV. Claims 80-81, drawn to a method of target-specific introduction of an exogenous gene into the genome of an organism.

XXXV. Claim 82, drawn to a method for detecting an altered zinc finger recognition sequence.

XXXVI. Claim 83, drawn to a method of diagnosing a disease.

XXXVII. Claims 84 and 85, drawn to a set of 256 separate oligonucleotides.

XXXVIII. Claim 86 a single stranded or double stranded oligonucleotide.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, IV, V, VII-IX, XIII, XVIII-XX, XXII-XXXII XXXIV-XXXV and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with different modes of operation, functions, effects, steps and/or components.

Inventions III, VI, X-XII, XIV-XVII, XXI, XXXIII, XXXVII and XXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

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and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds and/or components with different functions and/or effects or results.

Inventions (I, II, IV, V, VII-IX, XIII, XVIII-XX, XXII-XXXII XXXIV-XXXV and XXXVI) and (III, VI, X-XII, XIV-XVII, XX1, XXXIII, XXXVII and XXXVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods and different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search required for Group I is not required for Groups II-XXXVIII, specifically literature searches, restriction for examination purposes as indicated is proper.

Claims 1, 11, 20, 32,38, 45, 50,51, 55, 68, 69, 84 and 86 generic to a plurality of disclosed patentably distinct species comprising

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If Group I, is elected, applicants are to elect a single species from each of the following subgroups (i.e., one species from A, from B and so forth):

A. Screening a subset or individual members as recited in claim 1, step (b).

B. Transcriptional regulatory domain:

1. Transcriptional activator
2. Transcriptional repressor
3. Transcription factor recruiting protein

If Group II is elected, elect one species from each of the subgroups:

A. X (recited in claim 12)

1. Spi
2. SPIC
3. Zif 268

B. Mixtures

- 1.256 individual mixtures
2. Single mixture

If Group IV is elected, applicants are to elect a single species from:

A. Transcriptional regulatory domain:

1. Transcriptional activator
2. Transcriptional repressor



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3. Transcription factor recruiting protein

If Group V is elected, elect one species as follows:

A. X (recited in claim 12)

1. Spi
2. SPIC
3. Zif 268

If Group VII is elected, elect one species as follows:

A. Mixtures

1. Subset of members
2. Individual

If Group VIII is elected, elect one species as follows:

A. Effector domain or its activity as recited in claim 42 or claim 43.

If Group IX is elected, elect one species as follows:

A. Mixtures

1. 256 individual mixtures
2. Single mixture

If any one of Groups XI-XIII is elected, elect one species:

A single isolated ZFP i.e., a single peptide from the generic formula.

If Group XIV is elected, elect one species of enzyme as recited in 55 (b).

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If Group XXIII or XXIV is elected, elect one single proviso.

If Group XXXVII is elected, elect one species of a set.

If Group XXXVIII is elected, elect species of either single or double stranded oligonucleotide and specific structures.

Each of the species recited in each of the different subgroups e.g., subgroup A differs in structures and functions. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be

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examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D.   
T. D. Wessendorf  
Primary Examiner

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Tdw

December 12, 2003